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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/790,448	02/27/2004	Hiroshi Kido	2/187 PCT	9915

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EXAMINER

HAGOPIAN, CASEY SHEA

ART UNIT	PAPER NUMBER
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1615

MAIL DATE	DELIVERY MODE
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09/25/2007

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/790,448

Applicant(s)

KIDO, HIROSHI

Examiner

Casey Hagopian

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 16 July 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 10-13 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 10-13 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

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DETAILED ACTION

Receipt is acknowledged of applicant's Amendment/Remarks filed 7/16/2006.

Claims 10-13 are pending.

MAINTAINED REJECTIONS

The following rejections have been maintained from the previous Office Action dated 4/16/2007:

Art-based Rejections

Please note that **claims 10 and 11 are composition claims and any intended use recitation such as “for inhibiting proliferation of influenza virus in a warm-blooded animal” does not alone show patentable distinction.** A recitation of intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. In other words, if the prior art structure is capable of performing the intended use, then it meets the claim.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 10-13 stand rejected under 35 U.S.C. 102(b) as being anticipated by Mitra (WO 95/07103 A1). Mitra teaches compositions and methods for providing improved treatment, management or mitigation of cold, cold-like and/or flu symptoms by administering a safe and effective amount of a composition comprising an amino acid salts of propionic acid nonsteroidal anti-inflammatory agent along with at least one of (a) a decongestant, (b) an expectorant, (c) an antihistamine and (d) an antitussive (see Abstract and claim 1). Mitra also names the specific expectorants, "bromhexine and ambroxol, mixtures thereof or pharmaceutically acceptable salts thereof" (see claim 3). Mitra does not explicitly state the particular limitation "for inhibiting proliferation of an influenza virus" found in instant method claims 12 and 13, however Mitra teaches treating, management or mitigation of flu symptoms comprising the same ingredients. It is found that "inhibiting proliferation of an influenza virus" is inherent to Mitra's "treatment, management or mitigation of cold, cold-like and/or flu symptoms" because the method of Mitra and the claimed method are treating the same patient population. Thus, Mitra implicitly teaches the claimed method.

Claims 10-13 stand rejected under 35 U.S.C. 102(b) as being anticipated by Nilsen et al. (USPN 5,885,594). Nilsen teaches well-known orally administrable compositions for treating flu symptoms comprising expectorants such as ambroxol and pharmaceutically acceptable salts thereof (see col. 9, line 49 – col. 10, line 14). Nilsen does not explicitly state the particular limitation "inhibiting proliferation of an influenza virus" found in instant method claims 12 and 13, however Nilsen teaches treating flu

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symptoms comprising the same ingredients. It is found that “t inhibiting proliferation of an influenza virus” is inherent to Nilsen’s method of treating flu symptoms because the method of Nilsen and the claimed method are treating the same patient population. Thus, Nilsen implicitly teaches the claimed method.

Response to Arguments

Applicant’s amendment renders the objection to claim 13 moot. **Accordingly, the objection to claim 13 has been withdrawn.**

Applicant’s arguments, with regards to the rejection of claims 10-13 under 35 USC 102 in view of Mitra, have been fully considered but they are not persuasive. Applicant argues that Mitra does not teach the claimed composition and methods. The examiner respectfully disagrees. It is respectfully submitted that the claimed composition is disclosed by Mitra (Abstract; claims 1 and 3). The limitation “for inhibiting proliferation of influenza virus in a warm-blooded animal” is considered a future intended use and as such is not given patentable weight. Furthermore, the methods claimed do not clearly set forth a method step of administering the composition to a specific patient population. The method claims merely recite, “administering to a warm-blooded animal” which encompasses any patients including those who may be asymptomatic. Mitra teaches treating, management or mitigation of flu symptoms comprising the same ingredients. It is found that “inhibiting proliferation of an influenza

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virus" is inherent to Mitra's "treatment, management or mitigation of cold, cold-like and/or flu symptoms" because the method of Mitra and the claimed method are intending to treat the same patient population. Thus, Mitra implicitly teaches the claimed method. Thus, for these reasons the examiner respectfully disagrees with applicant's Remarks. **Accordingly, the rejection of claims 10-13 under 35 USC 102 in view of Mitra has been maintained.**

It is noted that applicant's Remarks do not contest the rejection of claims 10-13 under 35 USC 102 in view of Nilsen, thus for similar reasons as discussed above, said rejection has been maintained.

Conclusion

All claims have been rejected; no claims are allowed.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of

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the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Correspondence

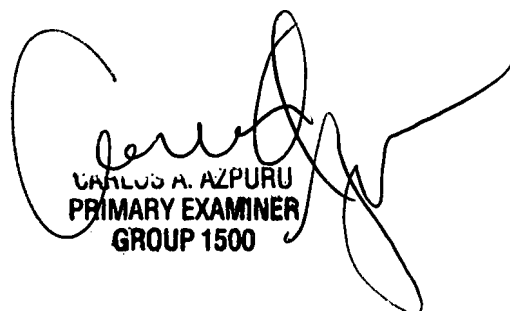
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Casey Hagopian whose telephone number is 571-272-6097. The examiner can normally be reached on Monday through Friday from 7:00 am to 4:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Carlos Azpuru, can be reached at 571-272-0588. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Casey Hagopian/

Casey Hagopian
Examiner
Art Unit 1615


CARLOS A. AZPURU
PRIMARY EXAMINER
GROUP 1500